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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	7

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/341,829	Lethe et al
Examiner	**Group Art Unit**
Minh-Tam Davis	1642

X Responsive to communication(s) filed on *Oct 18, 1999* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *1-7, 16-22, 24, 26, 29, 33, 38, 43, 45, 47, 49, and 53-56* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

X Claims *1-7, 16-22, 24, 26, 29, 33, 38, 43, 45, 47, 49, and 53-56* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

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--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

SEQUENCE RULE COMPLIANCE.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Applicant is given ONE MONTH, or THIRTY DAYS, whichever is longer from the date of this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821 (g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). In no case may an applicant extend the period for response beyond the SIX MONTH statutory period. Direct the response to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 6-7, 17-19, 38, 53, drawn to 1) a nucleic acid molecule of SEQ ID NO:4, a nucleic acid molecule that hybridizes under stringent conditions to SEQ ID NO:4, complements thereof, a vaccine composition comprising said nucleic acid molecule, an expression vector and a host cell, a unique fragment of SEQ ID NO:4, and 2) a method for diagnosing a disorder using an agent that binds to said nucleic acid molecule. It is noted that a method of claim 38 for diagnosing a disorder using an agent that binds to an expression product of SEQ ID NO:4 is not included in Group I. It is further noted that a vaccine composition of claim 53 comprising a nucleic acid molecule encoding an immunogenic fragment of SEQ ID NO:4 is not included in Group I.

Group II, claim(s) 1, 4-7, 17-19, 53, drawn to a nucleic acid molecule of SEQ ID NO:6, a nucleic acid molecule that hybridizes under stringent conditions to SEQ ID NO:6, complements thereof, an expression vector and a host cell, a unique fragment of SEQ ID NO:6, and a vaccine composition comprising said nucleic acid molecule.

Group III, claim(s) 53, 56, drawn to a vaccine composition comprising a nucleic acid encoding an immunogenic fragment of SEQ ID NO:4, and a nucleic acid encoding amino acids 142-148 of SEQ ID NO:5.

Group IV, claim(s) 53, 56, drawn to a vaccine composition comprising a nucleic acid encoding an immunogenic fragment of SEQ ID NO:4, and a nucleic acid encoding amino acid 187-205 of SEQ ID NO:5.

Group V, claim(s) 53, 56, drawn to a vaccine composition comprising a nucleic acid encoding an immunogenic fragment of SEQ ID NO:4, and a nucleic acid encoding amino acid 164-179 of SEQ ID NO:5.

Group VI, claim(s) 53, 56, drawn to a vaccine composition comprising a nucleic acid encoding an immunogenic fragment of SEQ ID NO:6, and a nucleic acid encoding amino acids 89-93 of SEQ ID NO:7.

Group VII, claim(s) 20-21, 54, drawn to an isolated polypeptide encoded by SEQ ID NO:4, or a polypeptide of SEQ ID NO:5, and a vaccine composition comprising SEQ ID NO:5.

Group VIII, claim(s) 20-21, 54, drawn to an isolated polypeptide encoded by SEQ ID NO:6, or a polypeptide of SEQ ID NO:7, and a vaccine composition comprising SEQ ID NO:7.

Group IX, claim(s) 22, 26, drawn to a unique fragment of SEQ ID NO:7, and amino acids 89-93 of SEQ ID NO:7.

Group X, claim(s) 24, 26, drawn to a unique fragment of SEQ ID NO:5, and amino acids 142-148 of SEQ ID NO:5.

Group XI, claim(s) 24, 26, drawn to a unique fragment of SEQ ID NO:5, and amino acids 187-205 of SEQ ID NO:5.

Group XII , claim(s) 24, 26, drawn to a unique fragment of SEQ ID NO:5, and amino acids 164-179 of SEQ ID NO:5.

Group XIII, claim(s) 29, drawn to a polypeptide that selectively binds to a protein encoded by SEQ ID NO:4.

Group XIV, claim(s) 29, drawn to a polypeptide that selectively binds to a protein encoded by SEQ ID NO:6.

Group XV, claim 33, drawn to a kit for detecting the presence of SEQ ID NO:4.

Group XVI, claim 33, drawn to a kit for detecting the presence of SEQ ID NO:6.

Group XVII, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a polypeptide encoded by SEQ ID NO:4.

Group XVIII, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a polypeptide encoded by SEQ ID NO:6.

Group XIX, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a polypeptide comprising amino acids 89-93 of SEQ ID NO:7.

Group XX, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a polypeptide comprising amino acids 142-148 of SEQ ID NO:5.

Group XXI, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a polypeptide comprising amino acids 187-205 of SEQ ID NO:5.

Group XXII, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a polypeptide comprising amino acids 164-179 of SEQ ID NO:5.

Group XXIII, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a unique fragment of SEQ ID NO:5.

Group XXIV, claim 43, drawn to a method for treating a subject, comprising administering an agent which enriches selectively complexes of a HLA molecule and a tumor rejection antigen derived from a unique fragment of SEQ ID NO:7.

Group XXV, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a polypeptide encoded by SEQ ID NO:4.

Group XXVI, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a polypeptide encoded by SEQ ID NO:6.

Group XXVII, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a polypeptide comprising amino acids 89-93 of SEQ ID NO:7.

Group XXVIII, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a polypeptide comprising amino acids 142-148 of SEQ ID NO:5.

Group XXIX, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a polypeptide comprising amino acids 187-205 of SEQ ID NO:5.

Group XXX, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a polypeptide comprising amino acids 164-179 of SEQ ID NO:5.

Group XXXI, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a unique fragment of SEQ ID NO:5.

Group XXXII, claim 45, drawn to a method for treating a subject, comprising administering cytolytic T cells specific for a unique fragment of SEQ ID NO:7.

Group XXXIII, claim 47, drawn to a method for treating a subject, comprising administering a polypeptide encoded by SEQ ID NO:4.

Group XXXIV, claim 47, drawn to a method for treating a subject, comprising administering a polypeptide encoded by SEQ ID NO:6.

Group XXXV, claim 47, drawn to a method for treating a subject, comprising administering a polypeptide comprising amino acids 89-93 of SEQ ID NO:7.

Group XXXVI, claim 47, drawn to a method for treating a subject, comprising administering a polypeptide comprising amino acids 142-148 of SEQ ID NO:5.

Group XXXVII, claim 47, drawn to a method for treating a subject, comprising administering a polypeptide comprising amino acids 187-205 of SEQ ID NO:5.

Group XXXVIII, claim 47, drawn to a method for treating a subject, comprising administering a polypeptide comprising amino acids 164-179 of SEQ ID NO:5.

Group XXXIX, claim 47, drawn to a method for treating a subject, comprising administering a unique fragment of SEQ ID NO:5.

Group XXXx, claim 47, drawn to a method for treating a subject, comprising administering a unique fragment of SEQ ID NO:7.

Group XXXXI, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a polypeptide encoded by SEQ ID NO:4.

Group XXXXII, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a polypeptide encoded by SEQ ID NO:6.

Group XXXXIII, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a polypeptide comprising amino acids 89-93 of SEQ ID NO:7.

Group XXXXIV, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a polypeptide comprising amino acids 142-148 of SEQ ID NO:5.

Group XXXXV, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a polypeptide comprising amino acids 187-205 of SEQ ID NO:5.

Group XXXXVI, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a polypeptide comprising amino acids 164-179 of SEQ ID NO:5.

Group XXXXVII, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a unique fragment of SEQ ID NO:5.

Group XXXXVIII, claim 49, drawn to a method for enriching a population of T cells with cytolytic T cells specific for a unique fragment of SEQ ID NO:7.

Group XXXXIX, claim 55, drawn to a vaccine comprising a cell which expresses a polypeptide encoded by SEQ ID NO:4.

Group XXXXX, claim 55, drawn to a vaccine comprising a cell which expresses a polypeptide encoded by SEQ ID NO:6.

In addition, upon the election of group VII, further election of the following patentably distinct species of the claimed invention is required:

A) SEQ ID NO:5,

B) SEQ ID NO:5 having substitution at residue 6,

C) SEQ ID NO:5 having substitution at residue 89,

D) SEQ ID NO:5 having substitution at residue 138,

E) SEQ ID NO:7 having substitution at residue 6,

F) SEQ ID NO:5 having substitution at residue 89.

The inventions listed as Groups I-XXXXX do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international stage application shall relate to one invention only or to a group of invention so linked as to form a single general inventive concept. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475 (d)).

Group I, claims 1-3, 6-7, 17-19, 53 form a single inventive concept of a nucleic acid of SEQ ID NO:4, and a method for diagnosis using an agent that binds to said nucleic acid..

Groups II-XVI, XXXXIX and XXXXX are additional products. Group II is distinct from group I, because SEQ ID Nos: 4 and 6 are different spliced variants of LAGE-1 antigen, having different structures. Further, the polynucleotides encoding immunogenic fragments of groups III-VI, are patentably distinct from SEQ ID NO:4 of group I, because each encoded fragment could independently elicit specific T cell production. Groups VII-XIV are patentabley distinct from group I, because they are drawn to polypeptides, which are structurally distinct from the nucleic acid of SEQ ID NO:4 of group I. Groups XV-XVI, drawn to a kit for detecting the presence of SEQ ID NO:4 or 6, which comprises additional reagents that are not found in group

I. Groups XXXXIX and XXXXX, drawn to a cell which is structurally and functionally distinct from SEQ ID NO:4.

The methods of Groups XVII-XXXXVIII differ from the method of group I and from each others in the method objectives, method steps and parameters and in the reagents used.

The species are distinct from each other, because they are structurally distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

December 10, 2000

SUSAN UNGAR, PH.D
PRIMARY EXAMINER